AQUEOUS OPHTHALMIC FORMULATIONS AND METHODS FOR PRESERVING SAME

Related Application

This application is a continuation-in-part of application Ser. No. 277,791, filed Nov. 29, 1988. The disclosure of this prior application is hereby incorporated in its entirety herein by reference.

BACKGROUND OF THE INVENTION

The present invention relates to preserving ophthalmic formulations or compositions, such as solutions. More particularly it relates to the use of stabilized chlorine dioxide to preserve ophthalmic formulations.

The use of contact lens has become widespread as a replacement for conventional eye glasses because of the improved vision obtained by the wearer or for aesthetic reasons. Contact lenses accumulate microorganisms and cellular debris from the eye. Thus, the lenses must be periodically removed and cleaned to prevent irritation of the eye or infection. Formulations used in lens care must be preserved by some means to interdict introducing microbial contaminants onto contact lenses or into the eye. Disinfecting preparations are part of the regimen indicated for contact lens care.

Numerous ophthalmic formulations have heretofore been used with lenses. The composition of the ophthalmic formulation will often be dictated by the polymeric materials employed in the fabrication of the contact lens. Because of the chemical composition of most ophthalmic formulations, the contact lenses treated, e.g., disinfected, cleaned, soaked, and the like, in such formulations must be rinsed prior to placement in the wearer's eye to prevent irritation of the eye.

Problems have also been encountered in the use of the prior art ophthalmic formulations for the treatment of contact lenses in that such formulations often become contaminated or deteriorate when exposed to the atmosphere once the seal of he formulation container has been broken. Microorganisms and/or other impurities often contaminate the formulation which requires that the formulation be discarded. Thus, there exists a need for aqueous ophthalmic compositions having extended lives. In other words, there is a need for ophthalmic formulations which are effectively preserved without being irritating or otherwise damaging to the eye. It is to such preserved ophthalmic formulations and methods for preserving ophthalmic formulations that the present invention is directed.

Ratcliff U.S. Pat. Nos. 4,696,811 and 4,689,215 disclose the use of stabilized chlorine dioxide for the treatment and prevention of oral disease, for the reduction of malodor, as an anti-plaque agent, an anti-gingivitis and anti-peridontitis agent, as well as a denture soak. These two patents disclose the use of 0.005 percent to 0.02 percent stabilized chlorine dioxide in sterilized water as a contact lens soaking formulation. However, the patents are void of any teaching or suggestion that stabilized chlorine dioxide can be incorporated into an ophthalmic formulation as a preservative for such a formulation. In addition, the patents do not disclose the use of buffer or tonicity components.

Stockel et al U.S. Pat. No. 4,499,077 discloses an antimicrobial composition for soft contact lenses including an oxidizing agent such as an oxyhalogen compound, e.g., stabilized chlorine dioxide, or hydrogen peroxide, and a polymeric germicide, e.g., a quaternary ammonium polymer or an amino and/or imino polymer or salts thereof. Stockel et al U.S. Pat. No. 4,654,208 discloses an antimicrobial composition for contact lenses including an aqueous solution of a germicidal polymeric nitrogen compound and an oxidizing agent, e.g., chlorine dioxide, stabilized chlorine dioxide or hydrogen peroxide, to potentiate the activity of the germicidal polymeric nitrogen compound at low concentrations. The Stockel et al patents characterize the "polymeric germicides" and the "germicidal polymeric nitrogen compounds" as positively charged, nitrogen-containing cationic polymers, such as certain quaternary ammonium polymers and polymeric amino and/or imino compounds, e.g., polydiguanides. Neither of these Stockel et al patents relate to ophthalmic compositions without such positively charged, nitrogen-containing cationic polymers.

SUMMARY OF THE INVENTION

Broadly, the present invention relates to aqueous ophthalmic formulations containing an effective minor amount of stabilized chlorine dioxide to effectively preserve the ophthalmic formulation; a buffer component and a tonicity component. The present ophthalmic formulations are effectively preserved and can be used, e.g., in the contact lens care context, without causing irritation or discomfort to the eyes of the user of the formulations.

In one aspect, the present invention relates to aqueous ophthalmic formulations or compositions, for example, solutions, comprising water, e.g., as a vehicle; an amount, preferably from about 0.0002 or about 0.002 to about 0.02 weight/volume percent, of stabilized chlorine dioxide effective to act as the sole preservative in the formulation; at least one buffer component in an amount effective to maintain the pH of the formulation in the range of about 6.8 to about 8; and at least one tonicity component in an amount effective to maintain the formulation at an osmolality of at least about 200 mOsmol/kg, especially at a tonicity value substantially corresponding to the tonicity value of fluids of an eye. The present ophthalmic formulations preferably include substantially no, i.e., are substantially free of, germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers, for example, the quaternary ammonium polymers, the polymeric amino and/or imino compounds and their salts disclosed in the above-noted Stockel et al patents. More preferably, the present ophthalmic formulations are substantially free of any such positively charged, nitrogen-containing cationic polymers. To provide the ophthalmic formulations with a pH substantially corresponding to the pH of the fluids of the eye, the pH of the ophthalmic formulation can be adjusted, if required, by addition of an acid or a base.

Methods for preserving ophthalmic formulations are also disclosed.

DETAILED DESCRIPTION

Stabilized chlorine dioxide has been found to be effective as a sole preservative in preserving ophthalmic formulations or compositions. Thus, the present formulations include stabilized chlorine dioxide in an amount effective to act as the sole preservative in the formulations. Although one or more other preservatives may be present, it is preferred that the formulations include no other effective preservatives. In a particularly useful